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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,011

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Andreas Boehm

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,011	<b>Applicant(s)</b> BOEHM ET AL.	
	<b>Examiner</b> Annette F. Dixon	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/3/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is in response to the request for continued examination filed on December 10, 2008. Examiner acknowledges claims 1-34 are pending in this application, with claim 1 having been currently amended.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 10, 2008 has been entered.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP§ 608.04.

Specifically, claim 1 now recites the claim limitation "in the absence of any device to close the oropharyngeal velum"; however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the invention was filed. In fact, the term "oropharyngeal velum" is not present anywhere within the original specification of the instant invention. Examiner acknowledges the oropharyngeal region is also known as the oral airway. However, the terms related to the oral region such as the mouth or a mouthpiece are found on Page 4, Lines 20- 30 and Page 5, Line 20, do not give way to a teaching of the absence of a device closing the region. Applicant is reminded that "any negative limitation or exclusionary proviso must have basis in the original disclosure:" MPEP§2173.05(i). There is no specific recitation or support for "the absence of any device to close the oropharyngeal velum" in the original disclosure; and therefore, the subject matter added to claim 1 is considered new matter and must be cancelled from the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977); *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984); and *Ex parte Parks*, 30 USPQ2d 1234,1236 (Bd. Pat. App. & Inter. 1993).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3771

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-6, 8-10, 13-16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672).

As to Claims 1, 18, 29, and 30, Chantrel discloses a therapeutic aerosol device with a nebulizer device (2) with an aerosol generator (Column 4, Line 54 thru Column 5, Line 2) to which a gaseous medium for the generation of a main aerosol flow may be supplied from a supply device, and a pressure connection device (7) to supply pressure fluctuations which are superimposed on the aerosol main flow (51), and a nosepiece (2b) for supplying the aerosol into one of the two alae of the nose of a user connected to the nebulizer device (2). (Figure 1). Yet the Chantrel does not expressly disclose the use of a flow resistance device for use in the other of the two alae of the user's nose. However, at the time the invention was made the use of a flow resistance device was known. Specifically, Djupesland teaches the use of a flow resistance device in combination with a nose piece for the purpose of improving the deposition of aerosol particles in the nose and paranasal sinuses. (Page 19, Line 20 thru Page 20, Line 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chantrel to include a flow resistance device, as taught by Djupesland for the purpose of providing a positive pressure environment in order to assist in the delivery of medicament during treatment.

As to Claim 3, the system of Chantrel and Djupesland teaches a nosepiece is embodied at one end for attachment to a connecting piece in the nebulizer device and

at the other end for introduction into one nostril and the tight sealing of one of a user's nostril. Specifically, Djupesland teaches a nosepiece (30) for introduction into the nostril of a user and connected to a nebulizer (via medicament supply unit, 32). (Figure 3).

As to Claims 4 and 5, the system of Chantrel and Djupesland teaches the end of the nosepiece embodied for introduction into one nostril is embodied in the form of a truncated cone. Specifically, Djupesland teaches a truncated cone. (Figure 3).

As to Claims 6, 31, and 32, the system of Chantrel and Djupesland teaches a truncated cone shaped end of the nosepiece yet does not expressly disclose the connection angle. However, at the time the invention was made the angle of the truncated cone would be selected based upon the patient characteristics (neonate, child, adult, elderly) for the purpose of ensuring optimization of medicament in patient treatment. (Page 21, Lines 10-19). Moreover, Applicant has not asserted that the specific range recited provides a particular advantage, solves a stated problem or serves a purpose different from that of optimizing medicament delivery.

As to Claims 8 and 9, the system of Chantrel and Djupesland teaches a flow resistance device embodied for introduction into the other of the user's nostrils. Specifically, Djupesland teaches a flow resistance device (36).

As to Claim 10, the system of Chantrel and Djupesland teaches the flow resistance device includes a filter device. Specifically, Djupesland teaches a filter maybe utilized as a flow resistor (Page 15, Lines 13-14).

As to Claims 13-15, the system of Chantrel and Djupesland teaches the flow resistance device with a stopper in the form of a truncated cone. Specifically,

Djupestrand teaches a flow resistance device (36) and a truncated cone (40) with a first diameter on the top of the cone and a second diameter on the base of the cone.

(Figure 3).

As to Claims 16, 19-21 and 33, the system of Chantrel and Djupestrand teaches pressure fluctuations during the administration of treatment utilizing the aerosol device. Specifically, Chantrel teaches air is pulsed via air source (pump, 4); which provides a gas source to the nose piece (2b). (Figure 1).

As to Claim 22-24, the system of Chantrel and Djupestrand teaches a sensor device for determining the aerosol flow or pressure fluctuations. Specifically, Djupestrand teaches a sensor (43) coupled to a control unit (44) for controlling the flow rate of aerosol for the purpose of optimizing the particle deposition efficiency within the nasal airway. (Page 21, Line 1 thru Line 19).

As to Claim 25, the system of Chantrel and Djupestrand teaches the use of multiple medicaments in the use of the nebulizing device. Specifically, Djupestrand teaches the use of multiple medicaments including the administration of decongestants, anti-histamines, cromoglycates, steroids, and antibiotics. (Page 2, Lines 3-10).

As to Claim 26, 27 and 34, the system of Chantrel and Djupestrand teaches the particle distribution size of the delivered medicament. Specifically, Djupestrand teaches the particle distribution size within the range of about 1 to 10 micrometers. (Page 6, Lines 1-2).

As to Claim 28, the system of Chantrel and Djupestrand teaches a handheld device. Specifically, Djupestrand teaches the medicament supply unit (32) can be

incorporated into a metered dose inhaler, which is a handheld device. (Page 18, Line 18-24).

7. Claim 2, 11, 12, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) as applied to claim 1 above, and further in view of Brugger (DE3238149).

As to Claim 2, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a suction channel. However, at the time the invention was made the use of a suction channel was known. Specifically, Brugger teaches the use of a suction channel in order to control the flow of the liquid droplets administered. (Page 3, Line 10 thru Page 4, Line 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to include the suction channel, as taught by Brugger to enable control of the medicament administration to the patient.

As to Claims 11 and 12, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the connection of the flow resistance device to the nosepiece. However, at the time the invention was made the use of a connection element between the two elements placed within the nose were well known, as taught by Brugger (Figure 1) to enable close placement of the device for operational use. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland



to include a connection piece between the elements, as taught by Brugger, to enable the device to be compact and connected.

As to Claim 17, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a meandering airflow channel. However, Brugger teaches the channel formation enables a smooth laminar transition from the airflow unit to the medicament to be delivered to the patient. As well known in the art, medicament is best administered to a patient in laminar flow rather than turbulent flow. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to provide a means for transitioning the airflow profile of medicament delivered to the patient, as taught by Brugger for the purpose of ensuring optimal treatment.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) as applied to claim 1 above, and further in view of Landis et al. (5,687,715).

As to Claim 7, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a balloon on the nose piece for the purpose of providing a seal to the patient's nose. However, at the time the invention was made the use of a balloon seal in a nasal interface was known. Specifically, Landis teaches a balloon (130) for insertion into the nares of a patient for the purpose of providing a sealing engagement and enabling patient comfort. (Figure 6

and Column 7, Line 55 thru Column 8, Line 18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupestrand to include a balloon seal, as taught by Landis for the purpose of providing patient comfort.

### ***Response to Arguments***

9. Applicant's arguments filed December 10, 2008 have been fully considered but they are not persuasive. Applicant asserts the combination of the prior art made of record does not disclose or teach the claim limitation of the flow resistance device "in the absence of any device to close the oropharyngeal velum". Examiner respectfully disagrees with Applicant's assertion. Though the device of Djupestrand discloses two nosepieces and a mouthpiece, as the mouthpieces of Figures 3 and 4 lack connection to the associated nosepieces, there is nothing that would structurally preclude the embodiments of the nosepieces to be utilized without the mouthpiece. Further, as addressed previously, Applicant has not provided any support for this newly recited claim limitation in the disclosure as originally filed. Thus, in light of the aforementioned reasoning the rejection of the claims has been maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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